

PART III: CONSUMER INFORMATION

NorLevo®
Levonorgestrel Tablets
0.75 mg

This leaflet is part III of a three-part "Product Monograph" published when NorLevo® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about NorLevo®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

NorLevo® is an emergency or backup contraceptive.

NorLevo® can prevent pregnancy after a contraceptive accident (such as a broken condom) or when no form of birth control was used. Treatment is **most** effective if used in the first 72 hours (3 days) following unprotected sex.

NorLevo® cannot terminate an existing pregnancy. Although there is no scientific evidence that NorLevo® would harm a developing embryo, women who are already pregnant should not use the product.

NorLevo® should not be used in place of regular contraception.

What it does:

NorLevo® acts as an emergency contraceptive by stopping or delaying the release of an egg from the ovary, thus preventing sperm and egg from uniting (fertilization). NorLevo® is not effective once a pregnancy has started, that is once the fertilized egg has attached to the wall of the uterus. It cannot stop a fertilized egg from attaching to the womb.

NorLevo® can be used following any unprotected act of sexual intercourse, including:

- when no contraceptive method has been used,
- when a contraceptive method may have failed, such as:
 - forgotten, ruptured, misuse or slippage of condom;
 - missed oral contraceptive pill;
 - expelled intrauterine device (IUD);
 - early removal, breakage or dislodgment of a vaginal diaphragm or of a contraceptive cap;
 - failure to withdraw before ejaculation ;
 - sexual intercourse during the supposedly fertile period when relying on periodic abstinence (temperature method);
 - in cases of sexual assault (rape);
 - a delay in starting a new packet of oral contraceptives;
 - a delay in getting a scheduled contraceptive injection.

NorLevo® is not as effective in preventing pregnancy as the use of most other birth control methods (e.g. oral contraceptive pills, IUS's, IUD's).

When it should not be used:

Do not use NorLevo® if:

- you have a confirmed or suspected pregnancy;
- you are allergic to it, or to any of the components of its formulation (for list of components, see the section "What the nonmedicinal ingredients are");
- you have abnormal vaginal bleeding.

What the medicinal ingredient is:

Levonorgestrel

What the nonmedicinal ingredients are:

Anhydrous colloidal silica, lactose monohydrate, magnesium stearate, maize starch, povidone.

What dosage form it comes in:

NorLevo® tablets are supplied in a blister package containing 2 tablets of 0.75 mg levonorgestrel. The tablet is round and white with no marking.

WARNINGS AND PRECAUTIONS**Serious Warnings and Precautions**

NorLevo provides no protection against HIV/AIDS and other sexually transmitted diseases (STDs), such as syphilis, gonorrhoea, chlamydia, and herpes. If you are worried about whether you may have been infected with HIV/AIDS, or other sexually transmitted diseases, talk to your health care provider about your concerns and ask how you can protect yourself in the future.

If your period is delayed by more than 5 to 7 days, you should contact your doctor and have a pregnancy test done.

NorLevo® is for Emergency Contraceptive Use Only and should not be used on regular basis.

NorLevo® provides only short-term protection against pregnancy. Sexual activity that takes place after taking NorLevo can still result in pregnancy if no contraceptive is used. You must abstain from sex or use another barrier method of birth control until your next normal period to make sure you do not get pregnant.

BEFORE you use NorLevo[®] talk to your doctor or pharmacist if:

- you are allergic to levonorgestrel or any component of NorLevo[®] tablet;
- you are pregnant or breast-feeding;
- you have recent unusual vaginal bleeding (during your last cycle);
- known or suspected breast cancer;
- you have active liver disease or tumor
- you weigh 75 kg (165 lbs) or more.

INTERACTIONS WITH THIS MEDICATION**Drugs that decrease the efficacy of NorLevo[®] include:**

- Anticonvulsants (phenobarbital, phenytoin, primidone, carbamazepine)
- Rifubutin
- Rifampicin
- Griseofulvin
- Ritonavir
- Hypericum perforatum (St. John wort)
- Ulipristal acetate

If you are taking one of the above medications, and your period is delayed by more than 5 to 7 days after using NorLevo[®], you should contact your doctor and/or have a pregnancy test done.

Tell your doctor if you have taken NorLevo[®] within 3 days of a Pap test, as it may affect your results.

PROPER USE OF THIS MEDICATION**Usual Dose:**

NorLevo[®] may prevent pregnancy if the two tablets are taken together within 72 hours (3 days) and preferably with 12 hours, after a contraceptive accident or other unprotected sexual intercourse. You should not delay starting treatment. NorLevo[®] is more effective the sooner you start taking the tablets after unprotected intercourse.

Tablets should be taken with a glass of water.

If you vomit within three (3) hours after swallowing the tablets:

- If you can see the tablets in the vomit, you should purchase and take a second dose as soon as possible.
- If the tablets are not visible in the vomit, call your doctor or pharmacist as you might need another dose.

NorLevo[®] can be taken at any time during your menstrual cycle.

If you are sexually active and do not wish to become pregnant, you should use a reliable method of contraception on a regular basis. If you want more information about regular contraceptives or if you

are having trouble using a method, ask your health professional for help in choosing a method that works for you.

NorLevo[®] is less effective in women weighing 75 kg (165 lbs) or more and not effective in women weighing more than 80 kg (176 lbs). If your weight is 75 kg or more, ask your health professional for advice on alternative methods of emergency contraception.

Nursing mothers:

You should discontinue nursing for at least 8 h, but not more than 24h, after emergency contraception. Any milk expressed during this period should be discarded.

Important:

If more than 72 hours (3 days) have passed since unprotected sex occurred, NorLevo[®] may not be effective. See your health care provider as soon as possible to discuss other options.

NorLevo[®] is not as effective in preventing pregnancy as the use of most other birth control methods (e.g. oral contraceptive pills, IUS's, IUD's or condoms, etc.). It should not be relied on for routine birth control by sexually active women.

Overdose:

Contact your local poison control center or emergency room immediately. Symptoms of overdose may include nausea, vomiting, vaginal bleeding and may lead to menstrual cycle disturbances.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

NorLevo[®] can cause temporary side effects in some women. These side effects generally do not last more than 24 hours. If the symptoms persist (for more than 48 hours) or are severe, see your doctor.

Common side effects include:

- Nausea, vomiting and diarrhea,
- Dizziness, fatigue, headache,
- Abdominal pain,
- Breast tenderness,
- Delayed menstrual period,
- Spotting,
- Irregular bleeding
- Painful menses;
- Uterine pain.

Delayed menstrual period: If your period is delayed by more than 5 to 7 days after using NorLevo[®], you should contact your doctor and/or have a pregnancy test done.

Inform your doctor or pharmacist of any unwanted effect which is not mentioned in this insert.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Uncommon	– Itching and/or redness all over your body			√
	– Mouth or throat swelling			√
	– Cramping or severe pain in your stomach or belly			√
	– Unusual vaginal bleeding prior or at your next normal period			√

This is not a complete list of side effects. For any unexpected effects while taking NorLevo®, contact your doctor or pharmacist.

HOW TO STORE IT

Keep out of reach of children.

Store at room temperature (15-30°C) and protect from light. Keep container in outer carton.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to:
 - Canada Vigilance Program
 - Health Canada
 - Postal Locator 0701E
 - Ottawa, Ontario
 - K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.”

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.bayer.ca>

or by contacting the distributor Bayer Inc., at: 1-800-265-7382

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